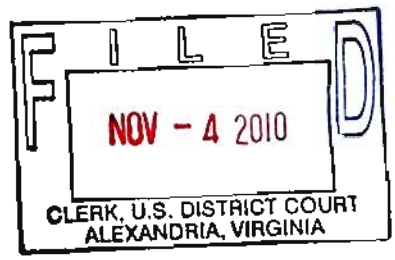
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division



GEORGIA TORKIE-TORK,	)	
Plaintiff,	)	
	)	
v.	)	**No. 1:04cv945**
	)	
WYETH,	)	
Defendant.	)	

MEMORANDUM OPINION

Plaintiff Georgia Torkie-Tork, in this removed diversity product liability action, sues defendant Wyeth for compensatory and punitive damages, alleging that Prempro, a drug manufactured and sold by defendant, caused her to suffer breast cancer. Defendant filed a timely motion for summary judgment, which was resolved by Memorandum Opinion dated October 4, 2010. *See Torkie-Tork v. Wyeth*, No. 1:04cv945, — F. Supp. 2d —, 2010 U.S. Dist. LEXIS 106819 (E.D. Va. Oct. 4, 2010) (Memorandum Opinion) ("*Wyeth I*"). As explained in that opinion, defendant won summary judgment, *inter alia*, on plaintiff's claim for fraudulent misrepresentation in the Prempro label, but not the claim for fraudulent concealment in the Prempro label. Defendant, it appeared, had inadvertently omitted facts and arguments directed to the fraudulent concealment claim. Acknowledging this inadvertent omission, defendant then sought leave to file a motion for partial summary judgment on the issue of fraudulent concealment, noting it could adduce additional undisputed facts that would demonstrate that defendant was entitled to judgment as a matter of law on this issue. For reasons of judicial economy, defendant was granted such leave and submitted a motion for summary judgment on the fraudulent concealment issue. *See Torkie-Tork v. Wyeth*, No. 1:04cv945, (E.D. Va. Oct. 12,

2010) (Order granting leave). That motion has been fully briefed and argued, and accordingly is now ripe for disposition.

I.

The undisputed facts of this case, with the exception of facts noted for the first time in the motion for partial summary judgment, are detailed in the previously published *Wyeth I*. *See Wyeth I*, 2010 U.S. Dist. LEXIS 106819, at *2-9. For the purposes of defendant's motion for partial summary judgment, the following additional facts are not in dispute.

On August 7, 2000, the FDA wrote defendant to request that certain changes be made to the label for E+P hormone therapy drugs, including Prempro. *See* FDA Letter to Wyeth (Aug. 7, 2000). Specifically, the FDA's proposed changes included the following statements:

> While some epidemiologic studies suggest a very modest increase in breast cancer risk for estrogen alone users versus non-users, other studies have not shown any increased risk. The addition of progestin to estrogen may increase the risk for breast cancer over that noted in non-hormone users more significantly (by about 24-40%), although this is based solely on epidemiologic studies, and definitive conclusions await prospective controlled clinical trials.
>
> . . .
>
> Studies examining the risk of breast cancer among women using estrogen alone and combined estrogen/progestin therapy have suggested that there may be a mildly increased risk of breast cancer in women taking the combined therapy.

After receiving this letter, defendant's counsel responded to the FDA, noting that the FDA did not have the power to "dictate proposed language for an applicant labeling without providing a meaningful opportunity for dialogue between the applicant and the agency." Arnold & Porter Letter to FDA (Nov. 7, 2000). Defendant also proposed alternative label revisions for the FDA's review with explanations for the areas of disagreement. Wyeth Letter to FDA (Aug. 11, 2000). For example, defendant stated:

> We strongly disagree with the presentation of the risk attributable to progestin use as 24-40%. First, we believe it is questionable for increases in risk to be stated

> only in percentages because this tends to exaggerate risk, particularly when absolute risk is small. Secondly, when stated only in this manner, the information is easily misinterpreted, i.e., one may interpret that 24-40% of all HRT users will develop breast cancer, a clearly inappropriate conclusion.

Defendant then proposed the following alternative language:

> Epidemiological studies suggest that the addition of progestin to estrogen therapy may enhance [the risk of breast cancer over estrogen-only therapy]. Definitive conclusions await prospective controlled clinical trials.

The dialogue between the FDA and defendant concerning Prempro label changes continued until March 2001, at which time the FDA approved final revisions to the Prempro label. Pl. Ex. 25. The final version of the language essentially reverted back to the FDA's original wording, but language was added concerning absolute risk, as defemdant requested, so as to contextualize the "24-40%" increase in risk in the FDA's language. Although the final revisions to this portion of the label dealing with cancer risks were approved in 2001, the FDA also had to review numerous other changes to the Prempro label. The final version of the label was not approved, in its entirety, until 2002, sometime after publication of the landmark WHI study showing a significant link between Prempro and breast cancer. The final version of the label incorporated additional changes in light of the WHI study, and the label was released in late 2002.

II.

The summary judgment standard is too well-settled to require elaboration here. In essence, summary judgment is appropriate under Rule 56, Fed. R. Civ. P., only where, on the basis of undisputed material facts, the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Importantly, to defeat summary judgment the non-moving party may not rest upon a "mere scintilla" of evidence, but must set forth specific facts showing a genuine issue for trial. *Id.* at 324; *Anderson v. Liberty Lobby, Inc.*, 477

U.S. 242, 252 (1986). Thus, the party with the burden of proof on an issue cannot prevail at summary judgment on that issue unless that party adduces evidence that would be sufficient, if believed, to carry the burden of proof on that issue at trial. *See Celotex*, 477 U.S. at 322.

III.

Plaintiff's fraudulent concealment claim alleges that defendant concealed the results of certain studies from the Prempro label that would have informed the public of the increased cancer risks associated with Prempro, particularly the 2000 studies by Ross and Schairer.[1] As noted in *Wyeth I*, defendant's correspondence with the FDA belies any inference of fraud:

> Wyeth carefully explained its concerns with the FDA's original draft of the revised warnings, and Wyeth ultimately reached an agreement with the FDA as to the appropriate changes to make. Had Wyeth implemented this agreed-upon revisions, it would be very difficult for plaintiff to meet her elevated burden to show fraud by clear and convincing evidence.

Wyeth I, 2010 U.S. Dist. LEXIS 106819 at *30. Nevertheless, it was not appropriate to grant defendant summary because the record showed that despite reaching an agreement as to the changes to the Prempro label, defendant did not actually implement those changes for more than a year. The record at that time provided no reason for this delay, and on that basis, defendant was denied summary judgment on the fraudulent concealment claim. *Id.*

The record now explains this gap in the timeline. The FDA indicated in March 2001 that "all revisions" to the Prempro label would have to be addressed before the changes could be implemented. *See* Letter from FDA to Wyeth (Mar. 6, 2001). Only by late 2002 did the FDA complete its revisions to the Prempro label as a whole, and only then could defendant release the updated Prempro label. As such, the record demonstrates that it was the FDA, not defendant,

[1] At oral argument on defendant's motion for summary judgment, plaintiff conceded that the only viable fraud claim was fraud in the Prempro label. *See Torkie-Tork I*, 2010 U.S. Dist. LEXIS 106819 at *2 n.4.

that delayed release of the new Prempro warnings. Furthermore, the studies that plaintiff claims were concealed from the FDA—the *Ross* and *Schairer* studies—were affirmatively disclosed to the FDA in a compendium of studies submitted to the agency on June 28, 2000. *See* Wyeth Transmittal to FDA (June 28, 2000).

Plaintiff argues that defendant intentionally impeded the FDA's review of the Prempro label by "papering" the FDA with multiple minor revisions, knowing that additional amendments would delay approval of the label as a whole. To support this assertion, plaintiff merely points to defendant's amendment submissions, as though one could infer from the mere fact of submitting amendments that the purpose of the amendments was to delay the approval process. No reasonable jury could make this leap and find, by clear and convincing evidence, that defendant acted fraudulently. Indeed, plaintiff fails to provide any evidence to indicate that the proposed revisions were frivolous or otherwise submitted for the purpose of delaying the FDA. As such, the record supports granting defendant summary judgment on the fraudulent concealment claim.

Plaintiff's brief also devotes significant attention to defendant's communications with doctors in an effort to show that defendant misled doctors about the cancer risks associated with Prempro. This evidence has virtually no probative value on whether defendant fraudulently concealed information *from the Prempro label.*[2] At best, such evidence is probative as to defendant's intent to mislead doctors as a whole. While this general intent might allow a jury to draw a slight inference about defendant's intent regarding disclosures on the Prempro label, this bare minimum of circumstantial evidence could not lead a reasonable jury to find fraudulent concealment by clear and convincing evidence.

---

[2] Of course, this evidence might be relevant to plaintiff's broader claim for negligent failure to warn, a claim that survives summary judgment and is not confined to the language of the Prempro label.

Because no reasonable jury could find for plaintiff on the fraudulent concealment claim by the requisite standard of clear and convincing evidence, it is appropriate to grant defendant summary judgment on this claim. As such, plaintiff's claims for negligent failure to warn and negligent design defect will be the only claims remaining for trial.

An appropriate Order will issue.

Alexandria, Virginia
November 4, 2010

/s/
T. S. Ellis, III
United States District Judge